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Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 11-44
Rockville, MD 20857

Re: FOSOMAX®

FDA Docket No. 96E-0036

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,621,077, which issued November 4, 1986. The application was filed on November 21, 1995, under 35 U.S.C. § 156.

A review of the record, including the response to the Order to Show Cause which was filed February 15, 1996 (a copy of which is enclosed herewith), reveals that the patent does claim the active ingredient of the approved product. Accordingly, the patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

(703) 305-9285

Enclosures:

Copy of Application for Patent Term Extension
Response to Order to Show Cause

cc: Melvin Winokur (without attachments)
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Rahway, NJ 07065-0907

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